VYGON
Value Life

VYGON - Prager Ring 100 - 52070 Aachen

Customer

[redacted]
Director Quality Management
and Regulatory Affairs

Tel.: 0241 / 91 30 0
Fax.: 0241 / 91 30 106
Email: [redacted]

Aachen, 20.02.2020

Urgent Recall on peristyl, Code 185.101, Batch No. 261119GF

We have identified a batch-related manufacturing problem, which lead to a discoloration of the catheter tube and a migration of the colorant to the catheter's surface.

The following product is involved in this recall:

Product Description	Code No.	Batch No.
peristyl	**185.101**	**261119GF**

We therefore ask you to immediately withdraw this batch from services and to return the batch according to our instructions below.

Please acknowledge receipt of this letter and complete and return the attached form by indicating the quantities withdrawn from your institution.

The Agency for Medicinal Products and Medical Devices of Croatia has been informed about this Field Safety Notice, FSN.

If you should require further information, please contact your local Vygon distributor via telephone number detailed below :

We apologize for any inconvenience this recall may cause.

Yours sincerely,

[redacted]

Director of Quality Management and Regulatory Affairs

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Urgent Recall on peristyl, Code 185.101, Batch No. 261119GF

ACKNOWLEDGMENT AND CUSTOMER RESPONSE FORM

Please complete and return this form:
by fax: xxxxxxxxxx or e-mail to : xxxxxxxxxx

Name and address of the institution :	
Full name of the person to contact:	
Function :	
☎ Phone number:	
E-mail:	

We acknowledge receipt of the above FSN and that the information contained in this field safety notice has been shared with all recipients / end users of above-mentioned products within our organization.

Please tick the appropriate box:

We have the following products available on stock :

Code 185.101, Batch 261119GE ❑Yes ❑ No If you have stock, number of units removed: _____

Signature and Date : _____

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Geschäftsführer / Managing Director
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Amtsgericht Aachen HRA 2523

Sparkasse Aachen
Kto.-Nr. 53 884 - (BLZ 390 500 00)
IBAN-Nr.: DE89 3905 0000 0000 0538 84
BIC Code: AACSDE 33

Postbank Köln
Kto.-Nr. 0211 680 508 - (BLZ 370 100 50)
IBAN-Nr.: DE59 3701 0050 0211 6805 08
BIC Code: PBNKDEFF370